

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

March 9, 2011
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:13 AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Gerard Dabney
David C. Kozera
Leo H. Ross
Ellen B. Shinaberry

MEMBERS ABSENT: Pratt P. Stelly
Jody H. Allen
Robert M. Rhodes

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Sammy Johnson, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

QUORUM: With seven members present, a quorum was established.

ANNOUNCEMENTS: Prior to introductions, Mr. Yi announced that Caroline D. Juran had been recently selected as the new Executive Director for the Board. Additionally, he announced that Sammy Johnson had assumed the position of Deputy Executive Director for the Board overseeing the licensure program.

APPROVAL OF AGENDA: An amended agenda was presented and approved by the Board which added discussions to review amended language in guidance document 110-30 regarding drugs within an animal shelter or pound and amended language in guidance document 110-9 regarding automated dispensing devices, USP 797 physical standards, and perpetual inventories.

APPROVAL OF MINUTES: The Board reviewed draft minutes for December 15, 2010; December 22, 2010; February 2, 2011; February 8, 2011; February 9, 2011; and February 23, 2011. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS:

There were no public comments made at this time.

DHP DIRECTOR'S
REPORT:

Mr. Yi stated that Dr. Cane could not attend the meeting due to a last-minute conflict which required her attention. Ms. Juran explained that Dr. Cane requested her to apologize to the board for her absence and share that her report was primarily to summarize activities related to the General Assembly which she believed Ms. Yeatts could cover in her report.

LEGISLATION:

Ms. Yeatts provided a summary of legislation from the 2011 General Assembly session that might be of possible interest to the Board. Additionally, she suggested the Board form a taskforce for promulgating emergency regulations for implementing provisions regarding continuous quality improvement programs as required in HB2220. There was agreement that at least three board members should participate on the taskforce, however, Mr. Yi did not make appointments at that time since three board members were absent.

Action Item:

The Board determined that Ms. Juran should send an email to all board members and key stakeholders soliciting participation on the taskforce for promulgating emergency regulations for implementing provisions regarding continuous quality improvement programs as required in HB2220 and that Mr. Yi would appoint interested persons to such taskforce.

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the emergency regulations for repackaging in community service boards and behavioral health authorities will expire on December 19, 2011, and therefore, the Board should consider adopting proposed regulations to continue this authority. Additionally, she reported that the effective date for the fast-track regulation regarding the signing of delivery records for automated dispensing devices in hospitals was listed incorrectly in the agenda packet. The effective date should be March 17, 2011. She also stated the elimination of an alarm system for certain EMS agencies is being handled as a fast-track regulation and that it is at the Governor's office for review. However, she was recently informed that regulation regarding administrative fees cannot be handled as a fast-track regulation and must adhere to the regular APA process.

Motion:

The Board voted unanimously to adopt proposed regulations for repackaging in community service boards and behavioral health authorities. (motion by Beckner, second by Ross)

UPDATE ON ACTION
ITEMS:

- Update on “on-hold” prescriptions

Ms. Juran reported that the ad hoc committee formed at the December board meeting for reviewing the possible need for regulations regarding on-hold prescriptions did not meet due to staff’s workload resulting from staffing shortages and commitments associated with the General Assembly. Therefore, she recommended that the full Board discuss the possible need for regulations and if needed, consider adopting the NOIRA as drafted by staff. The Board agreed the following concerns exist regarding on-hold prescriptions: prescriptions can be lost or stolen if data-entry and filing of prescription is not performed in a timely manner; verification of data-entry may not be performed by a pharmacist at the time it is entered into the computer; and many pharmacists believe the current requirement to file prescriptions by date of initial dispensing is burdensome since this requires the pharmacist to move the on-hold prescription from an original file to the file containing prescriptions initially dispensed that day. Therefore, the Board determined regulations are needed and the NOIRA was adopted as presented.

Motion:

The Board determined that regulatory action is needed to address concerns regarding on-hold prescriptions and voted unanimously to adopt the NOIRA as presented by staff. (motion by Kozera, second by Beckner)

MISCELLANEOUS:

- Guidance Document 110-34, submission of social security numbers or control numbers for wholesale distributors

Ms. Juran explained that current regulations governing wholesale distributors require the submission of social security numbers or control numbers issued by the Virginia DMV for each corporate officer and director. However, recently the Board has received requests from non-resident wholesale distributor applicants representing large corporations with many corporate officers to not provide the social security number of individuals who are not directly responsible for supervising the facility listed on the application and who do not have a control number issued by the DMV. At the time the regulation was enacted, concerns for identity theft were not as prevalent and significant concerns existed for some wholesale distributors operating illegally. The Board discussed the allowance to collect social security numbers or control numbers from individuals who are specifically responsible for the operations of the facility and not every officer and director. Staff presented the board with draft language to amend Guidance Document 110-34 which states the following individuals shall submit a social security number or control number: person serving as responsible party, and; individual owner or sole proprietor, or; each partner or corporate officer and director, who is specifically responsible for the operations of the facility listed on the

application.

Motion:

The Board voted unanimously to amend Guidance Document 110-34, as presented by staff, to limit the individuals who shall submit a social security number or control number when applying for a wholesale distributor permit. (motion by Ross, second by Dabney)

- Guidance Document 110-30, drugs within animal shelters or pounds

Ms. Juran explained that staff had been contacted recently by Dr. Dan Kovich, Staff Veterinarian for Animal Care and Health Policy, Virginia Department of Agriculture and Consumer Services. Dr. Kovich reported that confusion appears to exist within the animal shelters and pounds as to what drugs may be stored within the facility, when the drugs may be administered, and the role of the supervising veterinarian. Of particular concern was the allowance for certain Schedule VI drugs to prevent and treat certain communicable diseases as authorized in § 54.1-3423 E. Ms. Juran and Mr. Casway participated in a meeting to further discuss this matter. Because the Code does not define the required elements of a written protocol or training record when using certain Schedule VI drugs to prevent and treat certain communicable diseases and confusion appears to exist regarding requirements for stocking drugs for euthanasia compared to drugs for communicable diseases, the meeting participants determined that the Boards of Pharmacy and Veterinary Medicine should consider adopting a guidance document to clarify the allowances to purchase, possess, and administer drugs within an animal shelter or pound. Ms. Juran presented draft language resulting from this meeting which amends Guidance Document 110-30.

Motion:

The Board voted unanimously to amend Guidance Document 110-34, as presented by staff, to clarify the allowances to purchase, possess, and administer drugs within an animal shelter or pound. (motion by Kozera, second by Ross)

- Inventory requirements of drugs in Schedules II-V

The Board has received inquiries regarding whether the inventory of drugs in Schedules II-V must involve a physical count of the drugs or whether an estimation is permitted. The Board reviewed the inventory requirements listed in § 54.1-3404 and § 54.1-3434 of the Code, 18 VAC 110-20-240 of the Regulations, and 21 CFR 1304.11 and concluded that clarification should be provided. Ms. Juran reported that she is aware that North Carolina and Kentucky expect compliance with the federal allowance of physically counting all Schedule II drugs, but allowing for an estimation of drugs in Schedules III-V, unless the container holds more than 1,000 tablets/capsules. Concern was expressed for allowing an estimation of inventory when a theft or loss of drug had occurred. The Board concluded that those persons required in law to perform

an inventory of drugs shall physically count all drugs in Schedules II-V when a theft or loss of drug has occurred, but may otherwise perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules. It was acknowledged that nothing would prevent a person when performing an inventory from choosing to physically count all drugs in Schedules II-V.

Motion:

The Board voted unanimously that:

- **staff shall prepare a Guidance Document clarifying that those persons required in law to perform an inventory of drugs shall physically count all drugs in Schedules II-V when a theft or loss of drug has occurred, but may otherwise perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules;**
- **reference to performing a physical count in Major Deficiencies #13 and #14 of Guidance Document 110-9 shall be stricken; and,**
- **staff shall apply this guidance toward any open disciplinary cases involving the citing of Major Deficiency #13 or #14 related to inventory, wherein a physical count was not performed. (motion by Beckner, second by Dabney)**

- Status of pharmacy routine inspection program

Mr. Johnson provided statistics indicating the percentage of community pharmacies cited no deficiencies, deficiencies, and deficiencies that resulted in a monetary penalty covering a period of time from July 1, 2010 to February 28, 2011. Between July 1, 2010 and November 30, 2010, 42% of the inspected pharmacies were cited deficiencies that resulted in a monetary penalty. Between December 1, 2010 and February 28, 2011, 58% or 66 pharmacies were cited deficiencies that resulted in a monetary penalty. Of the 66 pharmacies, 46 were cited with Major Deficiency #15 regarding requirements for a perpetual inventory of drugs in Schedule II. Additionally, Mr. Johnson provided statistics for the hospital pharmacies where a pilot inspection had been recently performed. Between December 1, 2010 and February 28, 2011, 80% or 8 hospital pharmacies were cited a deficiency resulting in a monetary penalty. Of the 16 hospital pharmacies inspected between July 1, 2010 and February 28, 2011, 12 were cited for a Minor Deficiency #38 regarding automated dispensing devices.

- Guidance Document 110-9, perpetual inventories

There was discussion concerning the frequent citing of Major Deficiency #15 regarding perpetual inventories and recent examples

of pharmacists cited with the deficiency for performing the monthly perpetual inventory either one day before or after the applicable calendar month. After further discussion, the Board determined that Major Deficiency #15 should be amended to allow the monthly perpetual inventory to be performed as early as seven days prior to the applicable calendar month and as late as seven days after the applicable calendar month.

Motion:

The Board voted unanimously to amend Major Deficiency #15 in Guidance Document 110-9 to read “Perpetual inventory not being maintained as required; perpetual inventory performed more than seven days prior or more than seven days after designated calendar month for which an inventory is required” and to not apply this change to any disciplinary cases opened prior to March 9, 2011. (motion by Kozera, second by Beckner)

- Guidance Document 110-9, USP 797 physical standards

Mr. Johnson noted that during a recent pilot inspection of a hospital pharmacy, the pharmacy had a clean room but that not all physical requirements were compliant, e.g., ceiling, flooring. Ms. Juran stated that a monetary penalty of \$5,000 is imposed for Major Deficiency #21 when a pharmacy performing sterile compounding has no clean room, but there is no deficiency listed in the guidance document when the clean room does not comply with all physical standards of USP Chapter 797.

Motion:

The Board voted unanimously to add Major Deficiency #32 to Guidance Document 110-9 which would read “Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling” and to impose a \$2,000 monetary penalty when citing this deficiency. (motion by Shinaberry, second by Ross)

- Guidance Document 110-9, automated dispensing devices

There was discussion regarding the frequency in citing Minor Deficiency #38 regarding automated dispensing devices in hospitals. Ms. Juran informed the Board that she had been made aware that a petition for rulemaking to amend the applicable regulation would be received by the Board prior to the June 2011 board meeting. Therefore, it was suggested that the Board not take any action on this deficiency until it reviews the petition for rulemaking. Additionally, Ms. Juran noted that the inspection process will have been active for one year in June 2011 and that overall it has been a successful initiative, however, the Board may want a committee to review the deficiencies listed in Guidance Document 110-9 and make any necessary revisions prior to inspections going “live” in hospital pharmacies.

Action Item:

The Board determined that Ms. Juran should send an email to all board members soliciting participation on an ad hoc

committee to review the inspection process and the deficiencies identified in Guidance Document 110-9, and that Mr. Yi would appoint at least three board members to this committee.

- Agency Operating Efficiency Measures, sending agenda packets

Ms. Juran reported that the agency is attempting to increase electronic communication to reduce mailing costs and wanted to know if agenda packets for business matters could be scanned and sent via email, in lieu of mailing hard copies. The concept was generally accepted, although some may prefer a hard copy to be provided at the time of the meeting.

Action Item:

The Board determined that Ms. Juran should send an email to all board members to determine individual preferences for receiving agenda packets for business matters.

REPORTS:

- Report on DEA public meetings for surrender of unwanted controlled substances, National Take Back Day, PMP regulatory action

Ralph Orr, Program Director for Virginia's Prescription Monitoring Program (PMP) reported that he attended a public meeting conducted by the DEA on January 19-20, 2011 in Washington, D.C. The purpose of the meeting was to hear comments to assist DEA in developing regulations to implement the Secure and Responsible Drug Disposal Act of 2010 regarding procedures for the surrender of unwanted controlled substances by the ultimate user. Mr. Orr stated that there seemed to be a great deal of consensus on many facets of the issues to include the following:

- The need for a range of options for secure disposal of controlled substances and other pharmaceutical drugs-convenience and accessibility is essential;
- Take-back programs should be able to include both controlled and non-controlled substances without sorting them;
- Security of the medications to be disposed of is critical, including tracking of containers, tamper evident seals, locked containers, and other such measures;
- Regulations should not require that individual pills/vials/etc. be counted and logged. Many presenters suggested logging by weight;
- Allow different means of destruction of collected meds while contemplating hazard requirements; and
- Cost to consumers and states must be considered.

Mr. Orr reminded the members that the Board of Pharmacy had responded to a request for comment on several questions related to drug take back, disposal, and destruction from DEA in 2009, these comments along with others from that solicitation and the comments received at the public meeting will form the basis of regulations.

National Drug Take Back Day:

Mr. Orr announced that the DEA has declared April 30, 2011 to be the second National Drug Take Back Day. The first event held in September 2010 resulted in over 2.5 tons of unused/unwanted medications being turned in at over 82 sites across Virginia. There are already over 15 sites signed up for collection in the areas surrounding Richmond. Mr. Orr stated that the DEA is carrying the bulk of the financial burden for this project at this time with some hazardous waste incineration companies providing destruction services at no cost for this specific project. More information about the take back day and listings of collections sites may be found at: www.deadiversion.usdoj.gov.

PMP Interoperability Announcement:

Mr. Orr announced that Virginia and Ohio are the first states to sign a Memorandum of Understanding with the National Association of Boards of Pharmacy (NABP) to participate in NABP's new Interconnect Hub for PMP Interoperability. This new project from NABP is scheduled to begin a pilot phase in May and be fully operational in September 2011. The hub will be the conduit or switch that enables a user in one state to receive data from their home state PMP as well as other state PMPs that are participating in the hub without having to be registered in each state. However, each state PMP maintains control over the type of user who may receive PMP data from their program.

Regulatory Action Regarding PMP Reporting Requirements:

Mr. Orr explained that information has been posted on Virginia Town Hall for exempt regulations to be published March 14, 2011 in the Virginia Register. The regulations are exempt from the APA because the changes are directly related to minimum eligibility requirements necessary for federal grant funding. The changes in the regulation include a change from twice monthly reporting of data to once weekly, changing from ASAP Standard 95 to ASAP Standard Version 4.1. Additionally, specific data elements have been changed or added: 1. The Drug Enforcement Administration (DEA) registration number of the dispenser; 2. The total number of refills ordered; 3. Whether the prescription is a new prescription or a refill; and, 4. The date the prescription was written by the prescriber. These changes will become effective October 1, 2011. A new reporting manual detailing the updated reporting requirements is being developed and will be made available to dispensers within the next 60-70 days. Mr. Orr explained that these changes will keep the program eligible for funding to make enhancements to the program in the future, such as taking advantage of new technology and improving the use of the program for users.

- Report on Board of Health Professions

Mr. Kozera reported that the Board of Health Professions met on February 15, 2011. Discussions involved health care reform and a need for all boards to work toward meeting the needs of approximately 400,000 more patients who will be enrolled in Medicaid in 2014. Current scopes of practice should be evaluated in an effort to become more efficient at meeting the patients' needs. Additionally, Mr. Kozera reported that Dr. Cane discussed agency operating efficiency measures at the February meeting and the development of staff committees to review and possibly implement these recommended efficiencies. Mr. Kozera also stated that he has agreed to participate on the Regulatory Research Committee which is currently reviewing the possible need to license genetic counselors.

- Report on disciplinary matters

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of March 8, 2011, and stated that there were 274 cases docketed for the Board of Pharmacy. Three cases were at the entry level as just received; 59 cases at the enforcement level; 82 cases were at the board level (probable cause); 15 cases were with APD for the drafting of documents; one case was at the informal conference level; one case was at the formal hearing level and it was expected that the respondent would withdraw the appeal; and 113 cases were at the pending closure level wherein staff was expecting signed consent orders or confidential consent agreements.

- Executive Director's report

Ms. Juran stated that the contract for the administrator of the Virginia Federal and State Drug Law Exam had been awarded; the new contractor will begin administering the examination on July 1, 2011. The candidates' cost for taking the exam will increase slightly from \$100 to \$112, but she noted that it had been several years since this price was last adjusted.

Additionally, she reported that a Pharmacy Workforce Advisory Committee met on February 25, 2011, to begin drafting an online survey to assess workforce issues regarding pharmacists and, possibly, pharmacy technicians. Licensees will have the opportunity to complete the survey when renewing their licenses online this December. The committee will meet again in the next few months via teleconference.

It was also reported that the NABP Annual Meeting will be held May 21-24, 2011, in San Antonio, TX and that Ms. Juran plans to attend using travel reimbursement funds provided by NABP. She encouraged other board members to attend, but stated that the agency could not offer any travel money for their expenses.

Lastly, Ms. Juran stated that Mr. Kozera and Mr. Yi have informed her of a scheduling conflict with the September 7, 2011 board

meeting date; alternate dates were discussed. A tentative date of September 22, 2011 was set.

NEW BUSINESS

There was no new business discussed.

ADJOURN:

With all business concluded, the meeting adjourned at 1:05 p.m.

Caroline D. Juran
Executive Director

Date

Brandon Yi, Chairman

Date